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THE NATH LAW GROUP			ORWIG, KEVIN S	
112 South West Street			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,501	MUTA ET AL.	
	Examiner	Art Unit	
	Kevin S. Orwig	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 7/24/09.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-10 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-10 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application

6) Other: Exhibit A (translation of JP06256183).

DETAILED ACTION

The amendments and arguments filed Jul. 24, 2009 are acknowledged and have been fully considered. Claims 1-10 are now pending. Claims 1-7 are amended; claims 8-10 have been added. Claims 1-10 are now under consideration.

OBJECTIONS/REJECTIONS WITHDRAWN

The objections to claims 4-7 are withdrawn in light of the claim amendments.

The rejection of claims 1-3 under 35 U.S.C. 102(b) over MANABE is withdrawn in light of the claim amendments.

OBJECTIONS/REJECTIONS MAINTAINED

The rejection of claims 1-3 under 35 U.S.C. 103(a) over IIDA is maintained as discussed below.

The rejection of claims 1-3 under 35 U.S.C. 103(a) over MORI, WEISS, and OKAMOTO is maintained as discussed below.

Claim Rejections - 35 USC § 103 (Maintained)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over IIDA (JP 1991-161435; Published Jul. 11, 1991; 2nd Foreign reference on IDS dated May 25, 2005; English translation previously provided).

1. Iida discloses a patch that suppresses skin irritation (p. 3, middle par.). Iida exemplifies patches that comprise 0.2% capsicum extract, 0.5-1.0% l-menthol, and 1.0-10% polyethylene oxide (i.e. polyethylene glycol) (p. 14, Table 6). Thus, the only difference between Iida and the instant claims is that Iida does not exemplify a

composition comprising each of these components together and does not teach capsicum extract in the instantly claimed percent range.

2. Nonetheless, it is well within the skill of the ordinary artisan to combine or rearrange elements known in the prior art for a given purpose. For example, if an artisan wanted to make a patch of Iida's Example 10 (Table 6) having warming qualities, one would be motivated to add capsicum extract to the patch composition as taught by Iida, thus providing a warming composition as known in the art. The amount of warming material is clearly a result-effective variable that would be optimized by an ordinary artisan by routine experimentation based on the desired level of warming effect.

3. Regarding the instantly claimed percentage ranges, the MPEP states, "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)". In the instant case, there is no evidence of record to indicate that the claimed weight ranges and amounts for the various components are critical to the general function of the invention. For instance, paragraph [0020] of the instant specification clearly states that the amount of the warming material is not limited to the ranges disclosed as preferable. Likewise, paragraph [0022] of the instant specification states that the amount of l-menthol is not particularly limited. Claims 1-3 are rendered obvious over Iida.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that Iida exemplifies no patches containing all of the recited ingredients. Applicants argue that a skilled artisan would not combine capsicum extract with I-menthol because they have different functions (response, p. 8-9).

Applicants are reminded that the instant rejection was made under obviousness, not anticipation. The specific combination of features claimed is disclosed by Iida but such "picking and choosing" within several variables does not necessarily give rise to anticipation. *Corning Glass Works v. Sumitomo Elec.*, 868 F.2d 1251, 1262 (Fed. Circ. 1989). Where, as here, the reference does not provide any explicit motivation to select this specific combination of variables (i.e. capsicum extract with I-menthol and PEG), anticipation cannot be found.

However, it must be remembered that "[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR v. Teleflex*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. A.G. Pro*, 425 U.S. 273, 282 (1976)). "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (*Id.*). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take

account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR v. Teleflex*, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that “[a] person of ordinary skill is... a person of ordinary creativity, not an automaton.” *Id.* at 1742.

Consistent with this reasoning, it would have obvious to have selected various combinations of various disclosed ingredients (capsicum extract, l-menthol, and PEG) from within the prior art disclosure, to arrive at compositions “yielding no more than one would expect from such an arrangement.” It cannot be said that an artisan would never have combined capsicum extract, l-menthol, and PEG as applicants assert. This combination is prevalent in the art as evidenced by, for example, Manabe and Mori, for precisely the same reason suggested by the examiner. Applicants have provided no evidence to support their assertion (which goes against the prior art), and the argument that an artisan would not combine these ingredients is not persuasive.

Applicants argue that the skin irritation of lida is somehow different from the skin irritation referred to in the instant claims (response, p. 9).

Applicants are reminded that the instant claims are product claims, not method claims. Thus, any product comprising the same ingredients reads on the claim regardless of its intended use or function. In this case, the prior art patches contain PEG, which is recognized for its anti-skin irritation activity. This is an inherent property of the compound, and it would treat any skin irritation regardless of whether or not such an effect is recognized in the prior art. Thus the prior art patches would have the instantly claimed effect on skin irritation (residual or not). In response to applicants'

argument that the prior art does not recognize a benefit regarding residual skin irritation from using substantially the same patches, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Also, see MPEP § 2145: (Prima Facie Obviousness Is Not Rebutted by Merely Recognizing Additional Advantages or Latent Properties Present in the Prior Art) Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. *In re Wiseman*, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979)

It is also noted that while applicants argue that Iida proposes a patch having a support with a moisture permeability of 100-4000 g/m²/24h to solve the problem of skin irritation, applicants themselves claim the very same thing in claim 7. Thus, applicants point in making this argument is unknown.

Additionally, in response to applicants' argument that the references fail to show certain features of applicants' invention, it is noted that the features upon which applicant relies (i.e., that the irritation referred to by applicants is due to irritation after peeling the patch off, particularly that due to bathing) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants assert that the specific amounts for L-menthol and PEG are critical (response, p. 6).

Applicants provide absolutely no evidence to support this assertion. See MPEP § 2145(I). The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) (“An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a *prima facie* case of obviousness.”). However, the examiner has provided evidence that the claimed ranges are *not* critical. As stated in the prior Office Action, paragraph [0020] of the instant specification clearly states that the amount of the warming material is not limited to the ranges disclosed as preferable. Likewise, paragraph [0022] of the instant specification states that the amount of l-menthol is not particularly limited. Moreover, paragraph [0026] of the instant specification teaches much wider preferred ranges for the PEG component than the instantly claimed range; “preferably 3 to 25 mass %, but more preferably 5 to 15 mass %, based on the total amount of the adhesive layer 1.” In light of applicants’ own specification, it is clear that none of the percentage ranges instantly claimed are critical to the function of the invention.

Claims 1-3, newly examined claims 4 and 5, and new claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over MORI (JP 1981-010888; Published Oct. 11, 1981; English translation previously provided) in view of WEISS (U.S. 3,944,663; Issued Mar. 16, 1976) and OKAMOTO (JP 06-256183; Published Sep. 13, 1994; 2nd foreign reference on IDS dated Jun. 14, 2005, translation provided herein; see ‘Exhibit A’).

4. Mori discloses a heat stimulating patch with low skin irritation and a supporting base cloth (all of p. 2; last par. of p. 4). Mori teaches that capsicum extract is a useful heat stimulating component for the invention (p. 4, 3rd par.). Mori exemplifies patch compositions having both capsicum extract and l-menthol (p. 5, Examples 1 and 3). Mori does not discuss the appropriate percentage ranges of the warming component, but exemplifies the inclusion of warming components in amounts from 0.1-0.5% (Examples 1-3). Mori also exemplifies l-menthol in amounts from 0.3-1.3% (Examples 1-3). Mori teaches the use of 10-70% polyethylene glycol (p. 3, last par.). Mori exemplifies compositions comprising each of these components together (Examples 1 and 3). Thus, the only difference between Mori and instant claims 1-3 is that Mori does not *exemplify* PEG as the polyatomic alcohol component and does not teach *capsicum extract* in the instantly claimed percent range.

5. However, the disclosure of Mori clearly establishes the functional equivalence of the disclosed polyatomic alcohol components (e.g. glycerin and PEG) (p. 3, last par.). Thus, it would be obvious to substitute any of these for the exemplified compound (i.e. glycerin). Also, Mori teaches the inclusion of the warming component generally in a range of 0.1-0.5% (Examples 1-3). The heat stimulating property of Mori's patch is the point of the invention. However, besides the examples, Mori does not discuss the appropriate percentage ranges of the warming components. Thus, the artisan would expect some optimization of the amount of this component, which is clearly a result-effective variable. In light of Mori's disclosure, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use capsicum extract in an

amount of 0.1% since Mori teaches this amount as suitable for other warming components. Thus, one could have arrived at this amount by no more than routine experimentation. Furthermore, the skin irritation reducing properties of polyethylene glycol were recognized decades ago. As evidence, Weiss teaches that homopolymers of ethylene oxide (i.e. polyethylene glycol) act to reduce skin irritation (abstract; col. 1, lines 54-58; col. 4, lines 60-63).

6. Furthermore Okamoto discloses the use of polyoxyalkylene glycol as an irritation-reducing agent in a patch containing l-menthol and an irritation inducing NSAID (abstract). Okamoto discloses a patch comprising an adhesive layer containing indomethacin (an NSAID), l-menthol, and PEG having a molecular weight of 500-20,000. *PEG is specifically used as a skin irritation reducing agent* and is used in an amount of 7-55 wt. % (paragraph [0011]). Okamoto teaches that indomethacin is an outstanding NSAID that is used in the treatment of chronic arthritis (paragraph [0015]).

7. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have selected polyethylene glycol, particularly PEG having a molecular weight of 500-20,000, from the list of polyatomic alcohols taught by Mori to provide a warming patch with less skin irritation, which is precisely in line with the object of Mori's invention. One would have been motivated to do so since polyethylene glycol in this weight range was known to reduce skin irritation per the teachings of Weiss and Okamoto. Thus, the artisan would have had a high expectation of success in selecting polyethylene glycol for use in Mori's invention. It would further have been obvious for a skilled artisan to include an NSAID such as

indomethacin in the adhesive layer per the teachings of Okamoto. One would have been motivated to do so if the patch were intended to be used, for example, in the treatment of arthritis.

8. Furthermore, the amount of warming material is clearly a result-effective variable that would be optimized by an ordinary artisan by routine experimentation based on the desired level of warming effect. Regarding the instantly claimed percentage ranges, the MPEP states, "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)". In the instant case, there is no evidence of record to indicate that the claimed weight ranges and amounts for the various components are critical to the general function of the invention. For instance, paragraph [0020] of the instant specification clearly states that the amount of the warming material is not limited to the ranges disclosed as preferable. Likewise, paragraph [0022] of the instant specification states that the amount of l-menthol is not particularly limited. Claims 1-3, 4, 5, and 8-10 are rendered obvious over Mori, Weiss, and Okamoto.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants' arguments over Mori, Weiss, and Okamoto parallel those for Iida presented that have been addressed above, and that discussion is incorporated herein.

NEW GROUNDS OF OBJECTION/REJECTION

Claim Rejections - 35 USC § 112 (1st Paragraph)

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The response filed Jul. 24, 2009 has introduced NEW MATTER into the claims. Amended claim 1 recites a range of 10-25 mass % for the PEG component. However, written description support is lacking for this specific range of PEG. Applicants point to paragraphs [0024] (paragraph [0026] in the pre-grant publication) and Example 1 of the originally filed specification as allegedly providing support for this *range*. Example 1 teaches an exact amount (i.e. 10% of PEG). Paragraph [0024] teaches two ranges, namely 3-25% and 5-15%. Thus, support in the instant application is found for the ranges of 3-25% and 5-15%, but not for the instantly claimed range of about 10-25%, which represents a hybrid of one range and the example in the originally filed disclosure. There is nothing in the original disclosure that points to this specific combination of the range 3-35% and the single value used in Example 1. In the absence of support for the specific *range* of 10-35%, the recitations, "...the amount...of

said polyethylene glycol are...10-25 mass%, based on the total amount of said adhesive layer" in claim 1 is new matter and must be removed from the claims.

Instant claim 1 now recites limitations, which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in amended claim 1, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C 112. Applicant is required to provide sufficient written support for the limitations recited in present claim 1 in the specification or claims, as-filed, or remove these limitations from the claims in response to this Office Action.

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mori in view of Weiss and Okamoto as applied to claims 1-5 and 8-10 above, and further in view of Iida (JP 1991-161435).

9. The teachings of Mori, Weiss, Okamoto, and Iida are presented *supra*. Mori teaches the use of a base cloth support and Okamoto teaches the use of carriers such as thermoplastic resins that may take the form of films or laminates consisting of two or more layers (par. [0037]). The references do not teach the particulars support architecture and vapor permeability properties. However, it is within the purview of the skilled artisan to select the type of support layer most appropriate for a given patch.

10. An object of Iida's patches is to suppress skin irritation (p. 3, middle par.). Iida emphasizes the importance of a support layer having a moisture permeability in the range of 100-4000 g/m²/24h. Iida teaches an appropriate carrier support includes a polymer film sandwiched between two layers of unwoven fabrics (p. 3, last par. To p. 4,

3rd par.; Fig. 2). In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have selected the triple layer carrier support taught by Iida for use with Mori's patches. One would have been motivated to do so with a high expectation of success since both Iida and Mori are concerned with reducing skin irritation and since Iida teaches this support structure is suitable for doing so. Claims 6 and 7 are obvious over Mori, Weiss, Okamoto, and Iida.

Regarding the obviousness rejections herein, it is noted that a reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Summary/Conclusion

Claims 1-10 are rejected. No claims are allowed.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KSO

/David J Blanchard/
Primary Examiner, Art Unit 1643